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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/638,102	Applicant(s) SCHWARTZ, DAVID C. 3	
	Examiner Deborah A. Davis	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5-7,9-13,35,41 and 43-52 is/are pending in the application.
 4a) Of the above claim(s) 14-33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2,5-7,9-13 and 35 is/are allowed.
- 6) ☒ Claim(s) 41 and 43-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-13-05</u> . | 6) <input type="checkbox"/> Other: _____ |

MC

DETAILED ACTION

1. Applicants' response to the Office Action mailed on June 13, 2005 has been acknowledged. Currently, claims 41 and 43 through 52 are rejected and claims 35, 2, 5-7 and 9-13 are allowed.

Claim Rejections - 35 USC § 103

2 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

a. A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 41, 43, 45-46, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al (USP# 4,867,946) in view of Zuk et al (USP#4,281,061).

The instant claimed invention is drawn to a **chemical screening kit** which examiner still maintains applicant has not shown support for this limitation. The teaching of Gross et al was cited against the kit claims in the Office Action mailed October 19, 2004 and are set forth below for convenience.

Gross et al teaches the instant claims by teaching a device for evaluating test strips used to screen a variety of different samples. The test strips contain several test sections where the reagents are placed for testing (col. 1, 2nd para and see Figure 2). The device has a platform and a holder to support the test strips (col. 2, see claim 1) in

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a parallel relationship in which the test strips are perpendicular to the holder (see Figure 2). The test strip has test sections spaced along the strips to allow samples to be deposited (see Figure 2).

Although the reference of Gross et al teaches the components of the instant claimed invention, they are silent with respect to a kit.

However, Zuk et al. teaches that "as a matter of convenience the reagents can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the reagents and other materials as taught by Gross et al and format them into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit along with other materials. One in the art would be motivated to because the reagents in a kit are available in pre-measured amounts which eliminates the variability that can occur when performing the assay

4 Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Zuk and in further view of Adams (USP#6,156,494).

The teachings of Gross et al in view of Zuk et al are set forth above but is silent with respect to the strips being glass fibers.

However, Adams et al teaches methods for utilizing optical fibers as a solid support for the assembly of combinatorial compounds. The optical fibers are used to direct light, heat or a combination thereof (see abstract).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Gross et al to include glass fiber strips as taught by Adams et al to direct heat and light or a combination thereof to compounds on the surface of the fibers (see abstract) so compounds can be screened for binding activity.

5. Claims 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Zuk et al and in further view of Bensten et al ((USP#6,372,895).

The teachings of Gross et al are set forth above and differ in the instant invention because it does not particularly point out strips that include a marker selected from the group of printing and fluorescent material.

However, Bentsen et al teaches in one of his embodiments an apparatus that uses a test strip that contains a printed barcode wherein the printed material on the barcode has an enzyme or spore. The strip is further sterilized and dipped into a buffer solution containing Fluorescence Enzyme Substrate (FES). If enzyme activity is present, the printed pattern will become detectable (col. 20, lines 66-67 and col. 21, 1st para).

It would have been obvious to one of ordinary skill in the art to have incorporate the printed barcode as taught by Bentsen et al into the strips of Gross et al to detect enzyme activity.

Allowable Subject Matter

6. Claims 35, 2, 5-7, and 9-13 are allowed. Claims are allowable for reasons stated in the previous office action mailed October 19, 2005.

Response to Arguments

7. Applicant's argument that the word "kit " and the phrase "chemical screening kit" need not be found in the specification to be used in the claims. Applicant directs the examiner attention to the MPEP 2163.02, second paragraph, which recites:

The subject matter of the claim need not be described literally (i.e, using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement. Applicant further directs examiner attention to the patent of Venezia et al (USP#4,099,021), which claimed a kit, but the word kit was absent from its specification. Wherein its specification describes an assembly of parts.

Applicant also directs the examiner attention to the specification of the instant claimed invention, page 4, lines 8-12 that describes an assembly of strips in an array format which recites that its an improved tradeoff between mass production and flexibility is obtained. The examiner has found applicant's arguments to be persuasive. Therefore the rejection the 112, first rejection of written description is hereby withdrawn.

8. Applicant's argument that the reference of Gross does not teach all of the elements required by claim 41. Applicant asserts that the paper strips of Gross has

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identical linear arrays of chemically reactive substances as opposed to strips with "different arrays of chemically reactive substances, required by claims 41. The paper strips of Gross are individually exposed to different urine samples as opposed to the mutual exposure to a material to be screen, as required by claim 41. These arguments are noted but not found to be persuasive.

In response, the test strips of Gross are testing for bilirubin, urobilinogen, ketone bodies, ascorbic acid, glucose, protein, nitrite and others, therefore the test strips would contain different reagents, which is required by claim 41.

9. Applicant argues that the paper strips of Gross are individually exposed to different urine samples as opposed to the mutual exposure to a material to be screen , as required by claim 41. Applicant further argues that the frame of Gross is only used for photometric (light) analysis and does not teach a library/subset relationship. This argument is noted but not found to be persuasive.

In response, the test strips of Gross are in contact with urine for the detection of the variety of proteins recited above. Therefore, Gross uses a library of different strips, which meet the limitation of "subset of the library of strips" as required by claim 41. With respect to applicant's argument that the frame of Gross is only used for photometric (light) analysis, this teaching is not prohibited by the claimed invention. Further, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of

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performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

10. Applicant argument that the reference of Zuk does not remedy the deficiencies of Gross. Applicant argues that Zuk does not teach strips with different arrays of chemically reactive substances nor does Zuk teach mutual exposure to a material to be screened or teach a library of different strips placing them in a subset of library of strips. Applicant concludes that the combination of Gross in view of Zuk is not proper, and further argues that if it were proper, that the limitation of claims 41 has not been met. This argument is noted but not found to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

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Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the reference of Zuk was relied on for its teaching that reagents can be assembled together to form a kit for convenience of use. Further, kits are well known in the art. Therefore the 35 U.S.C. 103(a) rejection of claims 41, 43-52 are maintained.

Conclusion

11. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

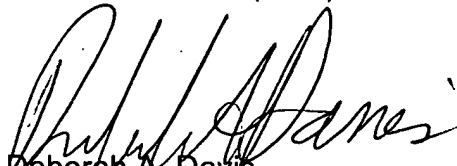
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

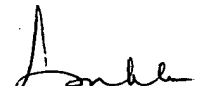
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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08/17/05